UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp, et al., Civil Action No. 07-10248-PBS	)	Hon. Patti B. Saris

UNITED STATES' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO THE ROXANE DEFENDANTS

Pursuant to Local Rule 56.1, the United States hereby submits its Statement of Undisputed Material Facts Applicable to the Roxane Defendants in Support of its Motion for Partial Summary Judgment. Additional Undisputed Material Facts, which are common to Abbott Laboratories, Inc., the Dey Defendants, and the Roxane Defendants, are set forth in a separate United States' Local Rule 56.1 Statement of Undisputed Material Facts Applicable to All Defendants, filed herewith.[1]

[1] The United States reserves the right to argue that, to the extent any particular statement of fact is genuinely disputed, it is immaterial.

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I. INTRODUCTION

1. The United States hereby incorporates by reference the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants ("US-C-SF"), filed this date.

2. Defendant Roxane Laboratories, Inc., n/k/a Boehringer Ingelheim Roxane, Inc. ("BIRI") is a corporation organized under the laws of the state of Delaware with its principal offices in Columbus, Ohio. In or around April 2005, Roxane Laboratories, Inc. changed its name from Roxane Laboratories, Inc. to BIRI. (United States' First Amended Complaint (hereinafter, "Amended Complaint"), ¶ 15 and Roxane's Answer and Defenses to the First Amended Complaint (hereinafter "Answer"), ¶ 15) BIRI continues to manufacture pharmaceutical products. (Corrected Roxane Local Rule 56.1 Statement of Undisputed Material Facts In Support of Its Motion For Summary Judgment (Dkt. No. 6207) (hereinafter "Roxane SOF"), ¶ 96)

3. Defendant Roxane Laboratories, Inc. is a corporation organized under the laws of Nevada, and was incorporated therein in or around April 2005. (Roxane SOF, ¶ 96) As of that time, Roxane Laboratories, Inc., assumed responsibilities for sales and marketing of pharmaceutical products sold under the Roxane trade name. (*Id.*) For the purposes of this Statement of Facts, BIRI and Roxane Laboratories, Inc. are referred to collectively as "Roxane."

4. Roxane's five-digit labeler code is 00054.

5. In or around 1991, Roxane signed a Medicaid Rebate Agreement with the Secretary of Health and Human Services. (Roxane SOF, ¶¶ 124-25)

A. The Drugs At Issue

6. The Amended Complaint alleges claims against Roxane arising from reimbursement paid by Medicare and Medicaid to providers for dispensing varying dosages, concentrations and sizes of nine Roxane products: azathioprine, diclofenac sodium, furosemide, hydromorphone, ipratropium bromide, Oramorph SR, Roxanol, Roxicodone and sodium polystyrene sulfonate (the "Subject Drugs"). (Amended Complaint, ¶ 58)

7. Although all of the Subject Drugs are multiple-source drugs, Roxane markets several of its products as "branded generics," meaning that Roxane assigns the products a "brand name" and markets them as "branded products." (Declaration of James J. Fauci in Support of Plaintiff's Motion for Partial Summary Judgment and in Opposition to the Roxane Defendants' Motion for Partial Summary Judgment (hereinafter, "Fauci") Exhibit 1 (5/21/2008 Mark Shaffer Dep.), at 66:11 - 67:3; Fauci Exhibit 2 (1/27/2005 Sheldon Berkle Dep.), at 129:11 - 129:20) Roxane distinguished internally between its "multi-source" products and its "branded generic" products. (*Id.*; *see also* Roxane SOF, ¶ 113)

8. The following are the NDCs for the Subject Drugs:

Subject Drug	**Formulation**	**Strength/Package Size**	**NDC**
azathioprine	Tablet	50 mg (100x) (10 x 10)	00054-4084-25
diclofenac sodium	Tablet	50 mg (100x) (10 x 10)	00054-4221-25
diclofenac sodium	Tablet	75 mg (100x) (10 x 10)	00054-4222-25
furosemide	Solution	60 ML	00054-3294-46
furosemide	Solution	120 ML	00054-3294-50

Subject Drug	Formulation	Strength/Package Size	NDC
furosemide	Tablet	20 mg 100s (10 x 10)	00054-4297-25
furosemide	Tablet	20 mg UD	00054-4297-25
furosemide	Tablet	20 mg 1000s	00054-4297-31
furosemide	Tablet	40 mg 100s (10 x 10)	00054-4299-25
furosemide	Tablet	40 mg 100s UD	00054-8299-25
furosemide	Tablet	40 mg 1000s	00054-4299-31
furosemide	Tablet	80 mg 100s (10 x 10)	00054-4301-25
furosemide	Tablet	80 mg 100s UD	00054-8301-25
furosemide	Tablet	80 mg 500s	00054-4301-29
hydromorphone	Tablet	2 mg 100s (4 x 25)	00054-4392-25
hydromorphone	Tablet	4 mg 100s (4 x 25)	00054-4394-25
ipratropium bromide .02%	Solution	2.5 ml 25s	00054-8402-11
ipratropium bromide .02%	Solution	2.5 ml 30s	00054-8402-13
ipratropium bromide .02%	Solution	2.5 ml 60s	00054-8402-21
ipratropium bromide .02%, NOVAPLUS	Solution	2.5 ml 25s	00054-8404-11
ipratropium bromide .02%, NOVAPLUS	Solution	2.5 ml 30s	00054-8404-13
ipratropium bromide .02%, NOVAPLUS	Solution	2.5 ml 60s	00054-8404-21
Oramorph SR	Tablet	15 mg 100s (4 x 25)	00054-4790-25
Oramorph SR	Tablet	30 mg 50s	00054-4805-19

Subject Drug	Formulation	Strength/Package Size	NDC
Oramorph SR	Tablet	30 mg 100s (4 x 25)	00054-4805-25
Oramorph SR	Tablet	30 mg 250s	00054-4805-27
Oramorph SR	Tablet	60 mg 100s	00054-4792-25
Oramorph SR	Tablet	100 mg 100s	00054-4793-25
Roxanol	Solution	20 mg/ml 30 ml	00054-3751-44
Roxanol	Solution	20 mg/ml 120 ml	00054-3751-50
Roxanol 100	Solution	20 mg/ml 240 ml	00054-3751-58
Roxicodone	Tablet	15 mg 100s (4 x 25)	00054-4658-25
Roxicodone	Tablet	30 mg 100s (4 x 25)	00054-4665-25
sodium polysyrene sulfonate O/S	Oral Sus	15 g/60 ml 500 ml	00054-3805-63
sodium polysyrene sulfonate O/S	Oral Sus	15 g/60 ml 60 ml 10s UD	00054-8816-11

B. Roxane's Customers, and Its Sales and Contracting Practices

9. Roxane sells the Subject Drugs to various classes of customers, including wholesalers, retail generic distributors, chain pharmacies, independent pharmacies, homecare pharmacies, hospitals and long term care facilities. (Fauci Exhibit 3 (Declaration of Simon Platt (hereinafter, "Platt Decl.")), ¶ 6; *see also* Fauci Exhibit 4, (3/2/2005 Christine Marsh Dep.) at 67:7 - 68:25)

10. Roxane sells its drugs through two primary distribution channels – direct sales and indirect sales. (Fauci Exhibit 3 (Platt Decl.), ¶¶ 4, 7) In a direct sale, Roxane invoices its customer for a product and then ships the product directly to that customer. (*Id.*) Wholesalers

and chain drug stores that warehouse their own product typically purchase products directly from Roxane. (Fauci Exhibit 4 (3/2/2005 Christine Marsh Dep.), at 67:18 - 68:6; Fauci Exhibit 3 (Platt Decl.), ¶ 9)

11. Roxane's direct customers generally purchase products at contractual prices, and are invoiced directly by Roxane. (Fauci Exhibit 3 (Platt Decl.), ¶ 7) Direct customers may also receive product discounts or price reductions in the form of rebates, special sale prices and/or other price adjustments which effectively reduce the net amounts paid for the product being purchased. (*Id.*, ¶ 8)

12. An indirect sale can be a sale that takes place between Roxane's wholesale customer and a contract customer who does not take direct delivery of the product from Roxane. (Fauci Exhibit 4 (3/2/2005 Christine Marsh Dep.), at 68:19 - 68:25; Fauci Exhibit 3 (Platt Decl.), ¶ 4) The indirect customer takes delivery of Roxane's product from the wholesaler. (Fauci Exhibit 3 (Platt Decl.), ¶ 10)

13. In an indirect sale with a contract, Roxane negotiates a contract with an indirect customer which sets forth the price between Roxane and the indirect customer. This contract price is nearly always less than the invoice price Roxane originally charges the wholesaler. (*Id.*; *see also* Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 148:20 - 149:10) In order to compensate the wholesaler for the shortfall that results from servicing indirect contract customers at prices below the wholesaler's original invoice price, the wholesaler is provided a credit for the difference, also known as a "chargeback." (Fauci Exhibit 3 (Platt Decl.), ¶ 10; *see also* Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 440:18 - 441:2; Fauci Exhibit 7 (12/1/2005 Edward DiPaola Dep.), at 75:22 - 76:10)

14. Wholesalers may also receive product discounts or price reductions in the form of rebates, special sales prices and/or other price adjustments which effectively reduce the net amounts paid for the pharmaceuticals. (Fauci Exhibit 3 (Platt Decl.), ¶ 11) Cardinal Health, Inc. ("Cardinal"), one of the three largest national wholesalers, measures its ultimate acquisition price of a product on a "dead net" basis, which is the price actually paid by Cardinal when factoring in rebates, chargebacks and other discounts. (Fauci Exhibit 8 (6/17/2008 Matthew Erick 30(b)(6) Dep.), at 118:11 - 119:22)

15. Cardinal does not charge indirect customers more than the contract price negotiated between the manufacturer and the indirect customer; instead, Cardinal honors the price as set forth in the indirect contract. (*Id.*, at 245:18 - 248:5) McKesson Corporation ("McKesson"), another of the three largest national wholesalers, also honors the indirect contract price negotiated between a manufacturer and its indirect contract customer. (Fauci Exhibit 9 (10/15/2004 Kimbir Tate 30(b)(6) Dep.), at 11:22 - 14:13)

16. Wholesalers profit from servicing indirect contracts through the manufacturer's payment of an administrative fee or rebate. (Fauci Exhibit 8 (6/17/2008 Matthew Erick 30(b)(6) Dep.), at 246:21 - 247:20)

17. Roxane was aware that wholesaler margins were typically less than 5%. (Fauci Exhibit 101 (Roxane "Reimbursement Background" memorandum), at Paoletti 20752 (noting that "a wholesaler's margin for most products is only a marginal 1% - 2% over their acquisition cost"); Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 208:7 - 210:5)

II. ROXANE REPORTED AWPS TO THE PRICING COMPENDIA FOR THE SUBJECT DRUGS

18. From at least 1996 to the present, Roxane reported Average Wholesale Prices ("AWPs") for the Subject Drugs to various pricing compendia, including Red Book, First Data Bank and Medi-Span. (Roxane SOF, ¶ 112; *see also* Fauci Exhibit 12 (11/17/2004 Richard Feldman Dep.), at 190:1 - 190:19; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 518:11 - 518:14; Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 94:10 - 95:5, 245:1 - 245:12; Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 67:7 - 67:9, 224:16 - 224:19)

19. Employees in Roxane's marketing department periodically reviewed price listings from First Data Bank to verify AWPs for Roxane's products. (Fauci Exhibit 24 (11/9/2004 Leslie Paoletti Dep.), at 108:21 - 109:18; Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 126:1 - 126:17; Fauci Exhibit 20 (10/24/2001 Judith Waterer Dep.), at 234:25 - 235:20)

20. Roxane employees similarly reviewed price listings from Red Book to verify Roxane's AWPs. (*See, e.g.*, Fauci Exhibit 21)

21. Roxane typically reported AWPs to the pricing compendia at the time of a product's launch and whenever AWPs changed. (Roxane SOF, ¶ 112; *see also* Fauci Exhibit 22 (9/20/2005 Leslie Paoletti Dep.), at 81:15 - 85:10; Fauci Exhibit 23)

III. ROXANE'S REPORTED WACS TO THE PRICING COMPENDIA FOR SOME OF THE SUBJECT DRUGS AND FOR SOME TIME PERIODS

22. From at least 1996 to approximately December 1997, Roxane reported Wholesale Acquisition Costs ("WACs") for its "multi-source products" (including azathioprine, diclofenac sodium, furosemide, hydromorphone, ipratropium bromide and sodium polystyrene sulfonate) to

various pricing compendia, including First Data Bank and Red Book. (Roxane SOF, ¶ 113; *see infra* ¶¶ 119-125)

23. After December 1997, Roxane stopped reporting new WACs for its multi-source products to First Data Bank. (Roxane SOF, ¶ 113) As a result, Roxane's last reported WACs for these products continued to be published by First Data Bank until late 1999. (*See infra* ¶ 124)

24. In or around late 1999, Roxane instructed First Data Bank to stop publishing WACs entirely for its multi-source products. From that point onwards, WACs of $0.00 were published for these products instead. (*See infra* ¶¶ 132-136)

25. Roxane continued to report WACs for its "branded generic" products (including Roxicodone, Oramorph SR and Roxanol) throughout the relevant time frame. (Roxane SOF, ¶113; *see also* Fauci Exhibit 24 (11/9/2004 Leslie Paoletti Dep.), at 94:8 - 94:23; Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 128:8 - 128:17)

IV. ROXANE'S REPORTED AWPS WERE FALSE

26. The United States' expert, Simon D. Platt, CPA, has calculated Roxane's average sales prices ("ASPs") for the Subject Drugs, aggregating the sales transaction data on a quarterly basis, and net of chargebacks, rebates and discounts. Mr. Platt has calculated ASPs for Roxane's direct sales, and for Roxane's indirect sales. (Fauci Exhibit 3 (Platt Decl.), ¶¶ 12-16) The ASPs, to Roxane's indirect customers represent prices paid by customers who purchase Roxane's products from wholesalers. (*Id.*, ¶ 4)

27. Mr. Platt has also compared Roxane's ASPs to the AWPs and WACs published by First DataBank and Red Book, and has calculated the "spreads" on Roxane's drugs, i.e., the

percentage markup over Roxane's ASPs, aggregating the data annually. These calculations and comparisons show that Roxane's AWPs were substantially higher than the prices generally and currently paid in the market for Roxane's products. (*Id.*, ¶¶ 12-16 and accompanying graphs and summaries)

28. The AWPs that Roxane caused to be published for its ipratropium bromide products (NDCs 00054-8402-11, 00054-8402-21 and 00054-8402-13) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A1 and Summary A1) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 77.6% in 1996 (the year of launch), to 296.8% in 2000, to 494% in 2002. (*Id.*)

29. The AWPs that Roxane caused to be published for its azathioprine (NDC 00054-4084-25) product were substantially higher than the prices at which Roxane sold this product to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A2 and Summary A2) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for this product ranged from 95.6% in 1999 to 356.9% in 2002. (*Id.*)

30. The AWPs that Roxane caused to be published for its sodium polystyrene sulfonate products (NDCs 00054-3805-63 and 00054-8861-11) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A3 and Summary A3) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 194.5% in 2000 to 196.1% in 2002. (*Id.*)

31. The AWPs that Roxane caused to be published for its Oramorph SR products (NDCs 00054-4793-25, 00054-4792-25, 00054-4805-25, 00054-4790-25, 00054-4805-27 and 00054-4805-19) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A4 and Summary A4) Specifically, the spread between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 69.4% in 1999 to 72.3% in 2000. (*Id.*)

32. The AWPs that Roxane caused to be published for its furosemide products (NDCs 00054-4299-31, 00054-4297-31, 00054-4301-29, 00054-3294-46, 00054-4301-25, 00054-3294-50, 00054-8299-25, 00054-4297-25, 00054-4299-25, 00054-8297-25 and 00054-8301-25) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A5 and Summary A5) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 156.8% in 1999 to 1411.9% in 2001. (*Id.*)

33. The AWPs that Roxane caused to be published for its hydromorphone products (NDCs 00054-4394-25 and 00054-4392-25) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A6 and Summary A6) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 241.1% in 1999 to 314.3% in 2001. (*Id.*)

34. The AWPs that Roxane caused to be published for its NovaPlus ipratropium bromide products (NDCs 00054-8404-11, 00054-8404-13 and 00054-8404-21) were substantially higher than the prices at which Roxane sold these products to the hospital class of trade. (Fauci Exhibit 3 (Platt Decl.), Graph A7 and Summary A7) Specifically, the spreads

between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 306.3% in 2000 to 440.7% in 2002. (*Id.*)

35. The AWPs that Roxane caused to be published for its Roxanol products (NDCs 00054-3751-50, 00054-3751-44 and 00054-3751-58) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A8 and Summary A8) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 211.6% in 1999 to 239.2% in 2000. (*Id.*)

36. The AWPs that Roxane caused to be published for its diclofenac sodium products (NDCs 00054-4222-25 and 00054-4221-25) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A9 and Summary A9) Specifically, the spreads between Roxane's AWPs and its ASPs for its indirect sales for these products ranged from 795.5% in 2000 to 1069.6% in 2001. (*Id.*)

37. The AWPs that Roxane caused to be published for its Roxicodone products (NDCs 00054-4665-25 and 00054-4658-25) were substantially higher than the prices at which Roxane sold these products to its indirect customers. (Fauci Exhibit 3 (Platt Decl.), Graph A10 and Summary A10) Specifically, the spread between Roxane's AWPs and its ASPs for its indirect sales for these products was 102% in 2000. (*Id.*)

V. ROXANE KNOWINGLY REPORTED FALSE AWPS FOR THE PURPOSE OF INCREASING REIMBURSEMENT TO PROVIDERS WHO PURCHASED ROXANE'S PRODUCTS

38. Roxane's stated practice was to set the AWP for its multi-source drugs at 10% below the AWP of the corresponding branded/innovator drug at the time of launch. (Roxane SOF, ¶ 99; *see also* Fauci Exhibit 20 (10/24/2001 Judith Waterer Dep.), at 242:22 - 243:14;

Fauci Exhibit 24 (11/9/2004 Leslie Paoletti Dep.), at 79:18 - 79:24, 147:20 - 147:25) For many products, however, including several of the Subject Drugs (e.g., hydromorphone), the AWP was *not* set at 10% below the corresponding brand's AWP at the time of launch. (*See, e.g.*, Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 587:16 - 58:6)

39. When Roxane set the AWP at 10% below the AWP of the corresponding branded/innovator product, it did so in order to increase reimbursement for its products. For example, an October 11, 1996 inter-office memorandum sent by Ms. Waterer to Mr. Tupa proposed increasing the AWP on metaproterenol (which is not a Subject Drug) as part of a "re-launch" of the product:

> Because this is a "re-launch" we already have a published AWP on the record. We have an opportunity to raise our AWP to 10% off the brand for the re-launch. This would provide us with a competitive advantage, particularly as the product does not appear to be subject to HCFA MAC pricing yet. In addition to being the innovator's generic, we could also be the most profitable product to the pharmacist.

(Fauci Exhibit 26) According to Ms. Waterer's memorandum, Roxane's three generic competitors had AWPs which were set *lower* than 10% off the branded AWP. Specifically, the branded AWP was $43.23, and Roxane's generic competitors' AWPs were $30.75, $29.95, and $34.40, respectively. (*Id.*) Ms. Waterer proposed that Roxane raise its AWP from $30.85 to $34.83 to gain the "competitive advantage," but she noted that Roxane could raise the AWP even higher (to $39.91), which would be 10% off the brand AWP. (*Id.*)

40. When launching a product into an "existing market," Roxane's stated practice is to set the AWP at a level comparable to competitors' AWPs. (Roxane SOF, ¶ 105; *see also* Fauci Exhibit 22 (9/20/2005 Leslie Paoletti Dep.), at 26:10 - 27:14) Mr. Russillo testified that

Roxane considered AWP spreads in setting and reporting prices. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 66:19 - 67:16)

41. Roxane states that it generally did not change the AWPs for its multi-source drugs following launch, but that it has raised its AWP to match those of competitors, either because Roxane's AWP was not set at 10% below the AWP of the branded/innovator product at the time of launch, or because competitors' AWPs had increased. (Roxane SOF, ¶ 106; *see also* Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 586:7 - 589:1; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 387:16 - 387:24; Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 252:9 - 253:22) Roxane raised the AWPs for several of the Subject Drugs, including hydromorphone (*see infra* ¶¶ 60-63), azathioprine (*see infra* ¶¶ 64-73) and furosemide (*see infra* ¶¶ 74-88).

A. The Launch of Ipratropium Bromide

42. Ipratropium bromide is the generic version of Atrovent Unit Dose Vial ("Atrovent"), a branded drug marketed by Roxane's sister company (BIPI). (Fauci Exhibit 28 (10/31/2008 Sheldon Berkle Dep.), at 77:1 - 77:5)

43. BIPI lost patent exclusivity on Atrovent in September 1996. (Fauci Exhibit 29, at ROX-TX 01341)

44. Roxane launched its generic ipratropium bromide product preemptively in June 1996, several months prior to other generic manufacturers being able to enter the ipratropium bromide market. (Fauci Exhibit 28 (10/31/2008 Sheldon Berkle Dep.), at 81:17 - 82:08, and at Berkle Dep. Exhibits 7 and 8) In launching generic ipratropium bromide, Roxane's objective was "to capitalize on the narrow window of exclusivity for [ipratropium bromide] in the targeted

markets, maintaining a majority of the market share for [the Boehringer Ingelheim Corporation]." (Fauci Exhibit 29 (4/17/1996 Ipratropium Bromide Launch Plan), at Rox-TX01343; Fauci Exhibit 28 (10/31/2008 Sheldon Berkle Dep.), at 111:6 - 111:16)

45. In or around January 1996, Roxane retained Mark Pope as a consultant to help with the launch of generic ipratropium bromide. (Fauci Exhibit 30 (4/14/2003 Mark Pope Dep.), at 67:25 - 68:17; Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 40:24 - 41:3, 45:1 - 45:22) Mr. Pope previously had worked for Dey Laboratories, and had experience marketing to the home health care market. (Fauci Exhibit 30 (4/14/2003 Mark Pope Dep.), at 42:3 - 42:9; Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 40:24 - 41:3)

46. On or about January 24, 1996, Mr. Pope met with representatives of Roxane and BIPI regarding the approaching launch of generic ipratropium bromide. (Fauci Exhibit 33, at RLI-AWP-00299558) The topic of "Medicare reimbursement" was discussed at the meeting including, specifically, whether Medicare reimbursed for the product using one or several "J codes." (*Id.*, at RLI-AWP-00299559 and RLI-AWP-00299562) BIPI previously had researched "Medicare Regions & Atrovent Solution Reimbursement" in late 1995 but in light of "contradictory information" on this topic, it was agreed that Mr. Pope would "verify reimbursement issues with his contacts within the industry." (*Id.*; Fauci Exhibit 110)

47. Following the January 24, 1996 meeting, Mr. Pope researched the home health care market, and met confidentially with "key homecare market customers" to confirm issues regarding packaging and pricing. (Fauci Exhibit 34) Mr. Pope reported his findings to Mr. Edward Tupa (then Roxane's Director of Multi-Source Marketing) including that "Medicare

reimbursement runs approximately 60%." (*Id.*, at RLI-AWP-00087618; Fauci Exhibit 35; *see also* Fauci Exhibit 32 (4/2/2003 Thomas Via Dep.), at 144:20 - 144:25)

48. Mr. Pope also reported that at least some home health care pharmacies were concerned about "reimbursement issues," (Fauci Exhibit 36), and that one pharmacy suggested that "AWP should be set at no lower than 20% less than the brand." (Fauci Exhibit 37) In his correspondence to Mr. Tupa, Mr. Pope stated that he thought setting the AWP at 10% less than the brand would be best. (*Id.*)

49. Subsequently, Thomas Via (then a Roxane National Account Manager) drafted the launch plan for generic ipratropium bromide, with input from Mr. Pope and Mr. Tupa. (Fauci Exhibit 38 (10/18/2005 Thomas Via Dep.), at 156:11 - 157:20)

50. In written comments to the draft launch plan dated April 9, 1996, Mr. Pope advised that it was "likely Roxane could capture a significant portion of the compounding market, providing the price provides a large enough 'spread' to maintain acceptable profit levels." (Fauci Exhibit 40, at ROX-CA 002096) Mr. Pope testified that he was "sure" his work as a consultant for Roxane included "encouraging Roxane to set and report AWPs and WACs that would allow it to create an attractive spread." (Fauci Exhibit 30 (4/14/2003 Mark Pope Dep.), at 119:11 - 119:15, 117:10 - 117:22)

51. The generic ipratropium bromide launch plan was finalized on April 17, 1996. (Fauci Exhibit 29) The launch plan described the pricing for generic Ipratropium Bromide as follows:

> Pricing of [ipratropium bromide] will need to follow the traditional parameters of a generic product. Specifically, AWP will be brand less 10%, or $44.06 for the 25 count package; WAC will be AWP less 40%, or $26.44 for the 25 count package. The reason this type of price structure is used for a generic launch is to

> create an attractive spread between WAC and AWP, encouraging accounts to convert from the brand name to the generic product as quickly as possible. This rapid conversion is necessary in order to protect our position in the market after generic competitors enter the market. It is felt that competitive pressures will drive large homecare pharmacies to purchase significant volumes of [ipratropium bromide], once the pricing is driven down to the $0.75 to $0.80 (.75=$18.75/25, .80=20.00/25) per vial level . . .
>
> . . . In a multi-source product launch, one of the most important keys to success is conversion from the brand to your first to market generic, as early as possible during your period of exclusivity. Again, this is done through enticing the accounts with an increased spread between WAC and AWP.

(*Id.*, at ROX-TX 01344)

52. Roxane launched its generic ipratrpium bromide product on or about June 3, 1996. (Fauci Exhibit 41) At the time of launch, Roxane planned to sell generic ipratropium bromide to warehousing chain pharmacies and home care pharmacies for approximately $23.80, compared to a reported AWP of $44.06. (Fauci Exhibit 29, at ROX-TX 01352; Fauci Exhibit 42)

53. A product announcement dated April 22, 1996 touted Roxane's ipratropium bromide as the first generic form of Atrovent and encouraged customers to "[c]ompare acquisition cost and AWP." (Fauci Exhibit 43) Other documents announcing the availability of generic ipratropium bromide identified the AWP and WAC, and invited customers to enter into sole source pricing agreements with Roxane. (*See, e.g.*, Fauci Exhibit 44; Fauci Exhibit 45)

54. On or about January 20, 1997, Roxane decreased the WAC for ipratropium bromide from $26.44 to $25.50 and, at the same time, announced an "Enhanced Ipratropium Bromide Loyalty Bonus Program" which doubled the rebates offered to certain customers. (Fauci Exhibit 46) Roxane did not lower the AWP for generic ipratropium bromide at this time.

(Fauci Exhibit 3 (Platt Decl.), Summary A1). The decrease in the WAC from $26.44 to $25.50 was published in First Data Bank. (*Id.*)

55. On or about December 1, 1997, Roxane again lowered its WAC for generic ipratropium bromide from $25.50 to $20.50. (Fauci Exhibit 47) Again, Roxane did not lower its AWP. (Fauci Exhibit 3 (Platt Decl.), Summary A1) Roxane did not report this WAC reduction to First Data Bank, as Roxane decided to stop reporting WACs to the pricing compendia in or around December 1997. (*See infra* ¶¶ 123-125; *see also* Fauci Exhibit 22 (9/30/2005 Leslie Paoletti Dep.), at 85:6 - 85:21; Fauci Exhibit 48) As a result, the $25.50 WAC continued to be published in First Data Bank. (Fauci Exhibit 3 (Platt Decl.), at Summary A1)

56. From 1996 through at least 2001, Roxane offered regular price reductions on generic ipratropium bromide, but Roxane never lowered the AWP. (Fauci Exhibit 3 (Platt Decl.), at Summary A1) Roxane's letters to customers announcing price reductions for its ipratropium bromide products frequently compared the offered contract price to the AWP. (*See, e.g.*, Fauci Exhibit 49; Fauci Exhibit 50; Fauci Exhibit 51; Fauci Exhibit 52)

57. For example, on or about July 20, 1999, Debbie Kutner (a National Account Manager) sent a Price Adjustment Request ("PAR") to the contracts department. The PAR noted that a customer had received a proposal from Dey Laboratories to supply ipratopium bromide at $11.00. Ms. Kutner recommended that Roxane "meet the competition and stay market competitive." (Fauci Exhibit 53)

58. Handwritten notes on the PAR state "Pls. create AWP. price red. doc 8-1-99 ____ 5-31-00." (*Id.*) The following day (July 21, 1999) Roxane sent a letter notifying the customer of

the price reduction and listing the new, reduced price to the customer next to the AWP. (Fauci Exhibit 54)

59. On October 2, 1998, Judy Waterer (then Roxane's Assistant Director of Multi-Source Marketing) sent an email identifying the AWPs and WACs for Roxane and Dey Laboratories' ipratropium bromide products. Ms. Waterer cautioned that "[t]hese are published prices only. The AWP and WAC have little relation to actual net selling price after chargebacks, discounts, rebates, etc." (Fauci Exhibit 55) (emphasis in original)

B. Roxane Raised the AWPs for Several Products Following Launch, Even When Sales Prices To Customers Were Not Increasing

1. Hydromorphone

60. In or around July 1998, Roxane determined that the AWPs for its hydromorphone 2 mg and 4 mg tablets (NDCs 00054-4392-25 and 00054-4394-25) were lower than those of competitors. (Fauci Exhibit 56, at RLI-AWP-00316337) According to a July 1998 monthly report, Roxane was losing market share on this product as a result of its "AWP being positioned incorrectly." (*Id.*) Roxane also determined that because the product was "still not MAC'd," Roxane's ability to sell the product was being "negatively impacted." (*Id.*)

61. A proposed AWP increase for hydromorphone was circulated in August 1998. (*Id; see also* Fauci Exhibit 57) The "AWP Increase Proposal" recommended raising the AWP on the 100 tablet (4 mg) hydromorphone product from $47.53 to $61.31. (Fauci Exhibit 57) The proposed AWP was slightly higher than the AWPs of two generic competitors, and significantly higher than the AWPs of the remaining competitors. (*Id.*) The proposal also noted that $61.31 was "the [] maximum AWP Roxane could assign based on brand AWP." (*Id.*)

62. On or about August 19, 1998, Roxane issued a product announcement, comparing the old AWPs to the new AWPs for its hydromorphone products. (Fauci Exhibit 58) The new AWP for the 100 tablet (4 mg) product was $61.31. (*Id.*)

63. Letters sent to customers announcing reductions in contract prices for these products listed the reduced prices along with the corresponding AWP. For example, a June 16, 1999 letter offered Cardinal a price of $14.70 on the 100 tablet (4 mg) bottle, compared to the AWP of $61.31. (Fauci Exhibit 59)

2. Azathioprine

64. On or about February 16, 1996, Roxane received approval to launch 50 mg azathioprine tablets (NDCs 00054-4084-25). (Fauci Exhibit 60) Promotional materials described Roxane's azathioprine product as the first generic form of Imuran, a brand drug. (Fauci Exhibit 61)

65. Roxane originally set the AWP and the WAC for a bottle of 100 (50 mg) azathioprine tablets at $111.24 and $77.90, respectively. (*Id.*) Roxane's announcements for these products listed the AWPs and WACs and encouraged customers to "[c]ompare acquisition cost and AWP." (*Id.*)

66. A February 19, 1996 Marketing Memo instructed Roxane's sales force to "go back over the Medicare selling message" when preparing sales calls.

> Simply stated, if a pharmacy buys Roxane azathioprine at $77 the Medicare reimbursement will represent a $40 profit ($117-$77 WAC) vs. $14 profit with Imuran ($117-$103 WAC). Remember, the Medicare reimbursement code K0119 is for azathioprine 50 mg tablets REGARDLESS OF MANUFACTURER!

(Fauci Exhibit 62) (emphasis in original)

67. In or around December 1996, Roxane increased prices the AWP and WAC for the 100 tablet bottle of azathioprine to $116.74 and $83.35, respectively. According to "a price increase analysis" sent by Ms. Waterer to Mr. Tupa on November 25, 1996, Roxane "kept the dollar amount of the spread as it was before the price change, so customers will still make the same amount per bottle." (Fauci Exhibit 63)

68. In or around December 1998, Roxane became aware that its competitor had raised the AWP for Imuran, the brand equivalent for azathioprine. (Fauci Exhibit 64) According to a "National Accounts Monthly Report" dated December 1998, customers wanted Roxane "to raise our AWP but not our price." (*Id.*) Mr. Sykora (then Director of National Accounts) wrote that this was:

> an opportunity to overcome two of the most common complaints heard for the lower than usual generic substitution rate for aza - too small a spread between awp and price on aza and too small a spread between imuran wac and aza wac[.]

(*Id.*, at BOEH01046914; Fauci Exhibit 65 (12/12/2008 Colin Carr-Hall Dep.), at 206:16 - 208:14) Roxane employees recognized that raising the AWP or lowering the price to customers would increase the "spread" and thereby make azathiprine more profitable to customers. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 142:2 - 145:17; Fauci Exhibit 66 (12/9/2008 Deborah Kutner Dep.), at 111:8 - 113:2, 116:10 - 119:10; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 162:1 - 163:1)

69. Roxane offered regular price reductions to customers for azathioprine throughout 1999. Letters notifying customers of these price reductions frequently compared the offered price to the AWP. (*See, e.g.*, Fauci Exhibit 67; Fauci Exhibit 68; Fauci Exhibit 69; Fauci Exhibit 70)

70. On or about September 10, 1999, Ms. Waterer sent a telefax to Thomas Russillo (then Roxane's Director of Multi-Source Marketing) containing an "azathioprine price analysis." (Fauci Exhibit 71) The analysis showed that Roxane's AWPs for its azathioprine products were lower than those of competitors. The analysis proposed raising Roxane's AWPs to as least as high as those of competitors. (*Id.*; Fauci Exhibit 72 (7/24/2007 Judith Waterer Dep.), at 811:22 - 813:1)

71. Also on September 10, 1999, Anthony Tavolaro (then, a National Accounts Manager) emailed Ms. Waterer asking for an "update" on the proposed AWP change for azathioprine. Mr. Tavolaro noted that a mail-order pharmacy was asking Roxane "to raise the AWP or lower our price to meet the spread." (Fauci Exhibit 180) Later that day, Mr. Russillo approved raising the AWPs for Roxane's azathioprine from $116.74 to $131.08. (*Id.*; Fauci Exhibit 73)

72. Mr. Russillo testified that he approved raising the AWPs for Roxane's azathioprine products to match competitors' AWPs, which had increased over time. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 293:18 - 294:17) Mr. Russillo also testified that increasing the AWPs provided a competitive advantage for Roxane. (*Id.*)

73. Subsequently, in late 1999 and 2000, Roxane continued to offer price reductions to its customers on azathioprine. Letters notifying customers of the price change compared the new offered price to Roxane's increased AWP. (*See e.g.*, Fauci Exhibit 74; Fauci Exhibit 75; *compare* Fauci Exhibit 75 *with* Fauci Exhibit 67)

3. Furosemide

74. In April 2000, several customers complained to Roxane that the AWPs for its furosemide products were "too low." (*See, e.g.*, Fauci Exhibit 76; Fauci Exhibit 76A; Fauci Exhibit 76B)

75. For example, on or about April 14, 2000, Mr. Sykora sent an email to Ms. Waterer notifying her that Caremark "would like to give" Roxane its furosemide business "except our AWP was far too low for it to be profitable for them." (Fauci Exhibit 76) Mr. Sykora noted that Roxane's AWP on one furosemide product was $45.25, while its competitors' AWPs were in excess of $140.00. (*Id.*) Mr. Sykora stated that "[t]his is certainly a hindrance to retail customers wanting to use our product. It would appear that an adjustment to the mid-140's [sic] is justified." (*Id.*)

76. Employees in Roxane's marketing department testified that Roxane was unable to sell its furosemide products during this time frame due to the fact that Roxane's AWPs were lower than those of competitors. (*See, e.g.*, Fauci Exhibit 77 (7/26/2007 Leslie Paoletti Dep.), at 77:10 - 80:8) As a result, Roxane considered discontinuing the product. (*See, e.g.*, Fauci Exhibit 78 (11/10/2004 Leslie Paoletti Dep.), at 195:8 - 196:1) According to Ms. Waterer, Roxane needed to "either discontinue the product or act like a competent marketer and do what everybody else in the industry was doing." (Fauci Exhibit 79 (11/28/2005 Judith Waterer Dep.), at 48:2 - 48:15; *see also* Fauci Exhibit 78 (11/10/2005 Leslie Paoletti Dep.), at 230:10 - 231:4)

77. On or about April 17, 2000, Ms. Waterer told Mr. Sykora that she would "look into" raising Roxane's AWPs for furosemide. Ms. Waterer also noted that "a significant price

increase may be a bit 'touchy' right now - especially since it's Furosemide (Mylan problems) and since AWP is what the compendia report with the most accuracy." (Fauci Exhibit 76) According to Ms. Waterer, raising the AWPs for furosemide presented an unusual situation, and required the involvement of "senior leadership" including her immediate supervisor, Mr. Russillo, as well as Mr. Russillo's supervisors. (Fauci Exhibit 79 (11/28/2005 Judith Waterer Dep.), at 48:19 - 51:1; Fauci Exhibit 80; Fauci Exhibit 81, at BOEH02708438)

78. On or about April 18, 2000, John Powers (then an employee in Roxane's Contracts Department) sent an email to Ms. Waterer, stating that while he appreciated her "comments regarding the sensitivity of a significant Furosemide increase at this time," Roxane had over 200 accounts for furosemide, and sales were significantly below expected levels. (Fauci Exhibit 76)

79. Ms. Waterer subsequently asked Mr. Sykora to prepare a "concise summary of customer comments, requests and documentation regarding Furosemide AWP." (Fauci Exhibit 80) In an email dated June 28, 2000, Ms. Waterer stated that Mr. Russillo (her immediate supervisor) was "aware of the issue and [] willing to champion it – provided we have an extremely solid and well documented background." (*Id.*; *see also* Fauci Exhibit 79 (11/28/2005 Judith Waterer Dep.), at 48:19 - 51:1) Ms. Waterer followed up with Mr. Sykora on July 7, 2000, and reiterated that Mr. Russillo was willing to support the AWP increase, "provided we have solid supporting information." (Fauci Exhibit 82)

80. Mr. Sykora responded to Ms. Waterer's inquiry as follows:

> I feel that you've thrown Furo onto my lap when the entire generic line AWPs need to be reviewed and adjusted. The most consistent complaint I hear from retail customers is [] our AWPs (which is better than a year ago when it was our service level). ***I realize there is political pressure on AWP currently but it***

> ***should not run our business. Logic dictates that no matter what the AWP is, if big brother wants to punish, they will so why not make some money meanwhile.*** We could have and should have changed the AWP on furo and other products months ago and no amount of documentation is going to mitigate the risk. I can put some documentation together but do not want to take my focus off of customers if we're not really serious about implementing AWP changes. Is this the real deal or busy work?

(*Id.*) (emphasis supplied)

81. Mr. Russillo responded to Mr. Sykora by email later that day. Mr. Russillo stated, "Bob, I assure it's real. To get the approval we need . . . we need some 'hard' info. Don't shoot the messenger, Judy is only doing what I asked her to do. Rich can assure you of the mood in BI." (Fauci Exhibit 83) Mr. Russillo testified that in order to support an AWP increase, he would have needed to see documentation showing that Roxane was matching the AWP of one of its competitors. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 165:15 - 166:9)

82. Mr. Russillo also testified that he was aware of government investigations into inflated AWPs by this time frame, (*id.*, at 54:19 - 54:22, 172:13 - 173:17) and that such investigations were a concern to him and to Boehringer Ingelheim in evaluating the proposed furosemide AWP increase. (*Id.*, at 166:7 - 166:9, 179:22 - 180:16) Mr. Russillo stated that he would not have endorsed the AWP increase for furosemide unless he believed it was authorized by his superiors. (*Id.*, at 172:18 - 174:4, 191:19 - 194:20, 221:22 - 223:1)

83. On or about July 26, 2000, Mr. Sykora submitted a "sales justification for an upward adjustment in the AWP of Furosemide." (Fauci Exhibit 84) The sales justification noted that a number of customers had rejected Roxane's bids for furosemide business due to Roxane's low AWP, which caused customers to have "worse profitability" when dispensing Roxane's

products. (*Id.*, at RLI-AWP-00330563) Mr. Sykora stated by that by raising its AWPs Roxane could "remove the barrier to securing additional Furosemide business from the customer's perspective." (*Id.*) Mr. Sykora also noted that had Roxane secured additional Furosemide accounts in 1999, it could have meant $610,000 to $6.1 million in increased revenue. (*Id.*, at RLI-AWP-00330565)

84. Roxane ultimately raised the AWPs on its furosemide product by as much as 300% in August 2000. For example, Roxane increased the AWP for its 1000 tablet (20 mg) product from $36.05 to $139.90. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 189:1 - 190:1; Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 109:1 - 110:13; Fauci Exhibit 85)

85. The sales justification memo drafted by Mr. Sykora stated that the contract price for the 1000 tablet (20 mg) product was approximately $10.00, compared with the new AWP of $139.90. (Fauci Exhibit 84, at RLI-AWP-00004514; Fauci Exhibit 3 (Platt Decl.), Graph A5 and Summary A5)

86. On or about August 2, 2000, Ms. Waterer sent an email to several personnel at Roxane, notifying them that "Tom Russillo just called me, and said he'd gotten the official OK to implement the Furosemide price changes recently circulated for approval." (Fauci Exhibit 85) Ms. Waterer informed Mr. Sykora that she was "really counting on your gang to deliver the $610,000 to $6,100,000 new business you committed to in the Opportunity section of your AWP assessment." (*Id.*)

87. During this time frame, Roxane's sales prices to customers for its furosemide products were not increasing. (Fauci Exhibit 3 (Platt Decl.), Graph A5 and Summary of A5; Fauci Exhibit 77 (7/26/2007 Leslie Paoletti Dep.), at 77:13 - 78:2)

88. On August 2, Mr. Sykora sent an email announcing new sales of furosemide:

> "Ask and ye shall receive! Based on the info. below, Hannaford Bros. awarded us Furo all strengths (2,000 bottles of furo 40mg 1000) and OptiSource has awarded us all strengths as well (unit volume being assembled). Steven is contacting CVS to see if there is still an opportunity to garner that biz. Crank up the machines, we're rocking on the furo train!!!!

(Fauci Exhibit 85) Several Roxane employees confirmed that furosemide sales increased following the the AWP increase. For example, Mr. Russillo testified that by raising the furosemide AWPs, Roxane increased the reimbursement paid to its customers, which helped Roxane win additional furosemide business. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 183:7 - 183:10, 315:8 - 316:2; Fauci Exhibit 78 (11/10/2004 Leslie Paoletti Dep.), at 207:4 - 208:1; Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 125:11 - 127:3)

C. Roxane's Branded Generic Products

1. Oramorph SR

89. Oramorph SR is a sustained release morphine product which Roxane marketed in the chronic pain/controlled release market. (Fauci Exhibit 86, at RLI-AWP-00170480; Fauci Exhibit 65 (12/8/2008 Colin Carr-Hall Dep.), at 66:13 - 66:18) Oramorph SR was a multi-source product and competed with MS Contin, a branded product marketed by Purdue Frederick. (Fauci Exhibit 86; *see also* Fauci Exhibit 65 (12/8/2008 Colin Carr-Hall Dep.), at 151:15 - 152:14)

90. Although Oramorph SR was a multi-source product, Roxane marketed it as a "branded generic." (Fauci Exhibit 31 (11/10/2005 Edward Tupa Dep.), at 110:10 - 110:14)

91. On or about March 30, 1995, Tom Via (then a National Account Manager) circulated a "Marketing Memo" to sales representatives announcing that Roxane was increasing its prices for Oramorph SR in response to a price increase for MS Contin. (Fauci Exhibit 87) Mr. Via explained that, prior to the price increases, Roxane's AWPs for Oramorph SR had been "40% over WAC," but now the AWPs were "43% more than the WAC." (*Id.*) Mr. Via noted:

> With our old 40% AWP pharmacists were making approximately 7% more when dispensing Oramorph SR instead of MS Contin. As a general rule, a pharmacist will now make around 15% more profit when they switch a prescription from MS Contin to Oramorph SR.

(*Id.*) The March 30, 1995 Marketing Memo also attached a worksheet "illustrating the impact on profit for the retailer with this change." (*Id.*) Mr. Via advised sales representatives that they should "be comfortable enough with the math that you can work the actual numbers out with the pharmacists." (*Id.*)

92. Mr. Via circulated another Marketing Memo related to Oramorph SR on or about January 31, 1997. (Fauci Exhibit 88) Mr. Via noted that Roxane was increasing the WACs and AWPs for its Oramorph SR products, again in response to price changes for MS Contin. (*Id.*) Mr. Via explained that as "our advantage on spread has increased slightly on all strengths and packages, this will provide an additional incentive for the retailer to stock and dispense Oramorph SR." (*Id.*) Mr. Via again advised sales representatives that "[w]hen presenting Oramorph SR at the pharmacy, first concentrate on this advantage between the spread and then on the cost savings to the patients." (*Id.*)

93. In January 1998, Roxane again raised the WACs and AWPs on its Oramorph SR products by 5%. (Fauci Exhibit 89) The increased WAC and AWP for the 100 tablet bottle (100

mg) (NDC 00054-4793-25) were $294.67 and $456.74, respectively. (*Id.*) According to a January 12, 1998 Memorandum, the fact that Oramorph SR had a greater AWP markup than MS Contin was "based on a strategy" Roxane "implemented several years ago, which was to posses a lower WAC price and offer significant profit advantage for retail pharmacies." (*Id.*, at RLI-AWP-00166210)

94. Roxane raised the AWP and WAC for the 100 tablet bottle (100 mg) again on or about January 1, 1999. (Fauci Exhibit 90) The WAC and AWP for the 100 tablet bottle increased to $309.40 and $479.58, respectively. (*Id.*)

95. On or about March 9, 1999, a Roxane employee sent an email announcing that Roxane had "lost" the spread advantage for Oramorph SR. (Fauci Exhibit 91) On March 10, Mr. Powers noted that "[t]his issue needs to be resolved." Mr. Powers stated that among the questions that need to be answered was "the financial/profitability impact if we lower our [Oramorph SR] prices without an AWP change to create a spread advantage over MS Contin[?]" (*Id.*)

96. On May 6, 1999, Mr. Powers announced that Roxane had lowered its contract prices for Oramorph SR. Mr. Powers wrote: "In order to compete with the new MS Contin prices appearing on [Long Term Care] and Hospice market contracts, Oramorph SR contract prices will be reduced to cover both price and spread differentials[.]" (Fauci Exhibit 92)

97. In early 2000, Roxane again increased the WACs and AWPs for its Oramorph SR products. The WAC and AWP for the 100 tablet bottle (100 mg) were increased to $316.68 and $493.95, respectively. (Fauci Exhibit 93; Fauci Exhibit 3 (Platt Decl.), Graph A4 and Summary A4) A Field Communication announcing the new prices to Roxane's palliative care sales force

included a pricing grid comparing prices for Oramorph SR and MS Contin. (Fauci Exhibit 93) The Field Communication instructed the sales force to "[u]tilize this pricing grid as a reference in your pharmacies to demonstrate the lower acquisition cost and higher spread for many of our products." (*Id.*)

2. Roxicodone

98. Roxane marketed "Roxicodone" as a "branded generic" product to treat chronic pain. (Fauci Exhibit 94; Fauci Exhibit 28 (10/31/2008 Sheldon Berkle Dep.), at 234:2 - 234:12) In or around September 2000, Roxane launched the "first and only" 15 and 30 mg Roxicodone tablets (NDCs 00054-4568-25 and 00054-4665-25). (Fauci Exhibit 94; Fauci Exhibit 95) Prior to September 2000, Roxane only marketed 5 mg Roxicodone tablets. (Fauci Exhibit 1, (5/21/2008 Shaffer Dep.), at 224:11 - 224:14)

99. On or about August 12, 2000, Fred Duy (then a director of "Business Development") sent the "Roxicodone 15/30 mg Launch Plan" to Sheldon Berkle (then Vice President of Marketing at BIPI) and others. At that time, Mr. Duy also transmitted an "initial pricing proposal for Roxicodone 15 and 30 mg Tablets." (Fauci Exhibit 94) The pricing proposal listed as "objectives" to set "reasonable price[s] relative to existing 5 mg tablets" and to ensure there was "no reimbursement incentive for substitution of 5 mg tablets." (*Id.*, at Shaffer 001516)

100. The proposed WAC and AWP for the 100 tablet bottle (15 mg) were $55.00 and $110.00, respectively. (*Id.*) According to the pricing proposal, "[t]he competitive spreads between WACs and AWPs in the class are significantly higher than the normal brand's 16 2/3% to 25%." (*Id.*) The pricing proposal stated that the proposed AWP prices for the 15 and 30 mg

Roxicodone products "will provide a similar spread for the pharmacy, so there is no incentive to substitute 5 mg tablets for 15 or 30 mg." (*Id.*; *see also* Fauci Exhibit 10, at RLI-AWP-00161992)

101. On or about August 22, 2000, WACs and AWPs for the Roxicodone 15 and 30 mg tablets were submitted for approval. The approval form stated that the proposed prices were "compatible with the reimbursement model that drives retailer profit." (Fauci Exhibit 97) Shortly thereafter, the proposed pricing was approved. (Fauci Exhibit 98)

102. Around this time frame, Mr. Sykora prepared a series of slides to present to Roxane's palliative care sales force in anticipation of the launch of Roxane's 15/30 mg Roxicodone tablets. (Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 133:7 - 135:13) One slide noted that Roxicodone 15 mg and 30 mg was typically more profitable for pharmacies to dispense. (Fauci Exhibit 99, at BOEH01301726) A "Roxicodone 15 mg, 30 mg profit calculator" also was created, showing the increased spread for Roxane's products. (Fauci Exhibit 100)

103. On or about September 8, 2000, Mark Shaffer (then head of Roxane's Palliative Care Sales Force) circulated a document entitled "Reimbursement Background." (Fauci Exhibit 101) The cover letter transmitting this document stated that "[k]nowledge of pharmaceutical reimbursement practices, especially how they may affect pharmacist acceptance for Roxicodone 15 mg and 30 mg tablets, will play an important part in your successful stocking of those new strengths in your retail accounts after the launch meeting." (*Id.*)

104. The Reimbursement Background memorandum included a section entitled "Pharmaceutical Product Reimbursement" which noted that "[a] reimbursement strategy that

assists the pharmacist in earning an equitable profit should ultimately pay dividends for the pharmaceutical manufacturer." (*Id.*, at Paoletti 20751) The memorandum also discussed the historical background of pharmacy reimbursement, and explained the role of WAC and AWP as follows:

> The WAC (Wholesaler Acquisition Cost) was the list price that pharmaceutical manufacturers charged wholesalers and often less than the list price to non-wholesale direct accounts. Wholesalers marked up their acquisition cost by 20% - 25% for resale to their pharmacy customers. These resale prices were referred to as Average Wholesale Prices (AWP) and were meant to reflect an average of suggested list prices that wholesalers charged various customer outlets (e.g., retail pharmacies and physician offices).

(*Id.*, at Paoletti 20751 - 52) The memorandum also described AWPs as "commonly used by retailers and others who dispense medications as the basis for many pricing decisions" and as "a surrogate for actual prices when studying prescription price trends." (*Id.*, at Paoletti 20756)

D. Roxane Promoted Reimbursement Spreads As An Inducement to Buy Its Products

105. As noted *supra*, Roxane's promotional literature frequently identified products' AWPs and invited customers to compare AWPs to acquisition costs. (*See supra* Paragraphs 53 and 65; *see also* Fauci Exhibit 43; Fauci Exhibit 61; Fauci Exhibit 22 (9/20/2005 Leslie Paoletti Dep.), at 85:22 - 87:19)

106. Roxane commonly provided contract prices and AWPs in its communications with customers. (*See, e.g.*, Fauci Exhibit 65 (12/12/2008 Colin Carr-Hall Dep.), at 121:2 - 122:1) Letters sent by Roxane notifying customers of price reductions frequently compared the offered contract price to the AWP. (*See supra* ¶¶ 53, 56, 63, 69, 73) For example, in or around, September 1999, Roxane reduced the price offered to one customer for ipratropium bromide to $14.40, not inclusive of market-share rebates. (Fauci Exhibit 50, at Kutner Deposition Exhibit 7)

The letter listed the $14.40 price next to the AWP, which was still $44.06. (*Id.*; *see also* Fauci Exhibit 50, at Kutner Deposition Exhibit 8; Fauci Exhibit 51; Fauci Exhibit 102)

107. When a customer asked that Roxane also include WACs in such letters, Roxane accommodated the request. For example, on or about April 13, 2000, a representative of ANDA Generics, a company with a business address in Florida, requested that "on all future offers, or price revisions [Roxane] list WAC, Contract Price, AWP." (Fauci Exhibit 103) Roxane agreed to do so, and future letters to ANDA Generics listed the WAC in addition to the contract price and AWP. (*See*, *e.g.*, Fauci Exhibit 104; Fauci Exhibit 105; Fauci Exhibit 106)

108. Roxane employees also promoted reimbursement spreads as a reason to buy Roxane's products. (*See e.g.*, Fauci Exhibit 107 (July 20, 2000 email from John Powers describing conversation with customer and stating "I discussed the AWP spread"); Fauci Exhibit 65 (12/12/2005 Colin Carr-Hall Dep.), at 128:5 - 128:22, 133:21 - 134:13; *see supra* ¶¶ 91 and 92; Fauci Exhibit 87; Fauci Exhibit 88)

109. For example, a National Accounts Monthly Report from May 1998 describes a promotion related to Oramorph SR, and notes that Colin Carr-Hall (then a National Account Manager) "will forward a full package of membership and contract pricing/AWP spread benefits for inside sales to capitalize on." (Fauci Exhibit 65 (12/12/2008 Colin Carr-Hall Dep.), at 169:22 - 173:4; Fauci Exhibit 135, at RLI-AWP-00327756) Mr. Carr-Hall testified that he created an information package including a "spread analysis grid of the incremental profit pharmacists can realize" and that the purpose of this grid was to show pharmacists that they could make more money supplying Oramorph SR than the competitor's product. (Fauci Exhibit 65 (12/12/2008 Colin Carr-Hall Dep.), at 174:3 - 176:5; Fauci Exhibit 133, at BOEH01046682)

110. Although Ms. Waterer testified in 2001 that she wouldn't "know how to begin to market a spread," (*see* Fauci Exhibit 20 (10/24/2004 Judith Waterer Dep.), at 180:20 - 180:25) the evidence establishes that Ms. Waterer was aware that sales representatives promoted "spreads" as a reason to buy Roxane's products and, moreover, that Ms. Waterer trained sales personnel how to do so. (*See, e.g.*, Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 104:1 - 105:19) For example, in a September 3, 1997 email, Ms. Waterer noted that sales representatives were emphasizing reimbursement advantages to customers when promoting a drug called meperidine:

> What will it take for us to get the meperidine?? . . . Our WAC is just about their dead net acquisition price from Barr already but our AWP's [sic] are higher than Barr's. This make our product more profitable for the pharmacies to sell - Not MAC'd yet!!! At similar pricing, we'll be preferred by the pharmacy - a fact our reps are not forgetting to mention!

(Fauci Exhibit 108) Likewise, according to an "Inside Sales Department November 1997 Monthly Report," Roxane ran a "mini-pilot on selling Azathioprine and Hydroxyurea using the spread between WAC and AWP." (Fauci Exhibit 109, at BOEH04556179) The report notes that Judy Waterer trained sales representatives on how to do so. (*Id.*) The Report explains that the sales personnel "started out with WAC vs. AWP in [the] message, but as they learn of a[n] acquisition cost from their customer they are adjusting their message." (*Id.*)

E. Roxane's Decision to Set Inflated AWPs Was Made With Knowledge That Medicare and Medicaid Programs Utilized AWPs in Setting Reimbursement

111. Roxane was familiar with the Medicare and Medicaid programs and regularly included information about Medicare and Medicaid reimbursement as part of its marketing documents. (*See, e.g.*, Fauci Exhibit 110 (November 1995 Interoffice Memorandum Regarding Medicare Regions); Fauci Exhibit 62)

112. For example, on or around November 14, 1995, Joseph Ashey circulated a memorandum entitled "Medicare Regions & Atrovent Solution Reimbursement." (Fauci Exhibit 110) The memorandum enclosed a "copy of a map reflecting the territories and states within each of the 4 Medicare reimbursement regions." (*Id.*) The memorandum also specified various "reimbursement rules by region[.]" (*Id.*) Roxane verified and incorporated the information included in this memorandum into its marketing strategies for ipratropium bromide (the generic equivalent of Atrovent). Specifically, Mr. Pope (a consultant hired by Roxane to help with the launch of ipratropium bromide) updated this research and reported his findings to Roxane's then Director of Multi-source Marketing (Mr. Tupa). (*See supra* ¶¶ 46-47; *see also* Fauci Exhibit 33, at RLI-AWP-00299562)

113. Roxane also included information about Medicare reimbursement in its marketing documents relating to the launch of azathioprine. (*See supra* paragraph 66) For example, a February 19, 1996 Marketing Memo references the Medicare reimbursement code for azathioprine, and encourages sales personnel to go over the "Medicare selling message." (Fauci Exhibit 62; Fauci Exhibit 111 (document entitled "Sales Strategy" and noting that "Roxane azathioprine, by virtue of its favorable pricing, has a distinct Medicare advantage") (emphasis in original))

114. Roxane regarded inclusion on state Medicaid formularies as important to the success of a product. (*See, e.g.*, Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 244:19 - 244:22; Fauci Exhibit 112 (6/25/2002 Richard Feldman Dep.), at 89:2 - 89:6; Fauci Exhibit 113 (12/3/2004 Jim King Dep.), at 125:1 - 126:9; Fauci Exhibit 65 (12/12/2008 Colin Carr Hall Dep.), 247:9 - 248:10; Fauci Exhibit 114 (12/16/2008 Fred Duy Dep.), at 188:6 - 189:3)

115. Roxane often referenced Medicaid programs as part of its marketing documents. For example, the launch plan for Roxane's 15/30 mg Roxicodone tablets included a "Medicaid Reimbursement Plan" outlining steps for notifying state Medicaid programs of Roxicodone's availability and for submitting requests that the products be added to state formularies. (Fauci Exhibit 94, at Shaffer 001490) Mr. Sykora (then the Director of National Accounts) prepared a series of slides to present to Roxane's palliative care sales force in anticipation of the launch of Roxane's 15/30 mg Roxicodone tablets. (Fauci Exhibit 11 (12/4/2008 Robert Sykora Dep.), at 133:7 - 135:13) One slide, entitled "Reimbursement," identified Medicaid as one of three patient payment types for Roxicodone (Fauci Exhibit 99, at BOEH01301724) and another slide noted that pharmacies were paid by Medicaid at either a "Maximum Allowable Cost (MAC)" or "AWP less %." (*Id.*, at BOEH01301725)

116. Roxane was aware that Medicare and many state Medicaid programs utilized AWPs in setting reimbursement, and that many third party payors, including Medicaid agencies, used First Data Bank to obtain AWPs. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 93:16 - 93:22, 129:11 - 130:1, 244:14 - 245:19; Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 50:10 - 50:19; Fauci Exhibit 112 (6/25/2002 Richard Feldman Dep.), at 88:2 - 88:12; Fauci Exhibit 99, at BOEH01301724 - BOEH01301725)

117. For example, in April 2000, Mr. Rowenhorst (then "Reimbursement Manager") circulated an email under the heading "Medicare reimbursement of Combivent UDV." (Fauci Exhibit 115) The email summarized Mr. Rowenhorst's "findings," including that Medicare reimbursement "is based on the AWP." (*Id.*; *see also* Fauci Exhibit 116) Mr. Rowenhorst also

specified that "generic products" were reimbursed at the "median of all generic AWPs" and he included examples of what Medicare would reimburse for certain drugs and dosages. (*Id.*)

118. Roxane was also aware that, at various times, First Data Bank defined AWP as follows:

> AWP is the average wholesale price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product (NDC). The operative word is average. AWP was developed to provide a price which all parties could agree upon for electronic pricing to be possible.

(Fauci Exhibit 117; *see also* Fauci Exhibit 101 (Reimbursement Background Memorandum), at Paoletti 20751-52 (stating that AWPs "were meant to reflect an average of suggested list prices that wholesalers charged various customer outlets."))

F. Roxane Took Steps To Ensure That Only Its AWPS Were Published For Certain of The Subject Drugs

1. Roxane Stopped Reporting New WACs for Its Multi-Source Products Contemporaneously with Its Decision to Lower WACs for Over 200 Products

119. Beginning in or around November 1997, Roxane began to evaluate the steps necessary "to reduce WAC pricing across the board to wholesalers[.]" (Fauci Exhibit 118; Fauci Exhibit 119; Fauci Exhibit 12 (11/17/2004 Richard Feldman Dep.), at 113:4 - 113:10)

120. According to a memorandum sent by Ms. Waterer to her then supervisor, Mr. Tupa, Roxane lowered WACs for over two hundred multi-source products in late 1997 and early 1998 to bring them "into line with the true prices that retail drug stores actually pay for the products." (Fauci Exhibit 120 (March 13, 1998 Inter-office Memorandum), at Rox 03041)

121. Ms. Waterer identified at least two rationales for implementing the WAC change. (*Id.*) First, prior to the change, Roxane's WACs were "as much as 8 to 10 times" higher than

products' "actual retail value." (Fauci Exhibit 120, at Rox 03041) Wholesalers had expressed "extreme displeasure" at having to be "rebated, or charged back as much as 80%-90% of the original purchase price." (*Id.*; *see also* Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 161:2 - 162:16) Second, Roxane paid certain rebates to customers as percentages of WAC. Because Roxane's WACs were "as much as 8 to 10 times" higher than some products' "actual retail value," the rebates paid by Roxane often were disproportionately large in relation to the selling price. (Fauci Exhibit 120, at Rox 0304; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 513:11 - 515:5)

122. On or about November 24, 1997, Roxane held a "Program Implementation Meeting" to discuss, among other things, the proposed WAC adjustment. (Fauci Exhibit 118) Prior to implementing WAC adjustments to its "full line" of multi-source products, Roxane elected to lower the WACs for its ipratropium bromide and ranitidine products as a "trial" or "pilot" run. (Fauci Exhibit 118; Fauci Exhibit 120; Fauci Exhibit 121; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 500:4 - 500:9, 505:17 - 505:23)

123. On or about December 1, 1997, Roxane lowered the WACs for two ipratropium bromide and three ranitidine products. (*See supra* ¶ 55; *see also* Fauci Exhibit 47) Roxane personnel referred to this as the "Baby WAC" adjustment. (Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 503:17 - 504:4)

124. On or before December 8, 1997 (one week after reducing the WACs for its ipratropium bromide and ranitidine products), Roxane decided to stop reporting WACs for its multi-source products to First Data Bank. (Fauci Exhibit 48) A December 8, 1998 email sent by

Cheri Mayhew (then Roxane's "Promotional Materials Administrator") to Judy Waterer stated as follows:

> I discussed with Kathy from First Data Bank, that we no longer want to publish or supply to them our WAC prices. It's okay with them that we do not supply the WAC price. However, there are approximately 10 states that use WAC for state Medicaid, instead of the AWP. She informed me that these states will use the last published WAC to determine state Medicaid for those states. So if we decide not to supply them with WAC for price increases they will use old pricing. She did not address new products.

(*Id.*)[2]

125. When Roxane decided to stop reporting WACs in or around December 1997, plans were already in place to reduce the WACs for over 200 multi-source products. (Fauci Exhibit 118; Fauci Exhibit 119; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 504:18 - 506:5) Roxane knew that if it did not report its new (reduced) WACs, First Data Bank would continue to report Roxane's last published (and higher) WACs. (Fauci Exhibit 48; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 213:13 - 214:5)

126. Roxane implemented its "full line" WAC change in March 1998. (Fauci Exhibit 120; Fauci Exhibit 122) Customers were notified on March 13, 1998. (Fauci Exhibit 123) The WAC changes were effective March 16, 1998, and encompassed 266 products in total with the WACs decreasing for 220 products. (*Id.*; *see also* Fauci Exhibit 120) Of the Subject Drugs, WACs were decreased for diclofenac sodium, hydromorphone and sodium polystyrene sulfonate (in addition to the ipratropium bromide WAC reduction discussed *supra* at Paragraph 54-55). (*Id.*)

[2] Consistent with this policy, Roxane did not report to First Data Bank its reduced WACs for ipratropium bromide. (*See infra* Paragraphs 54-55; Fauci Exhibit 3 (Platt Decl.), Summary A-1)

127. Although Roxane reduced the WACs for over 200 products, Roxane did not lower any of the corresponding AWPs. (*Id.*; *see also* Fauci Exhibit 124; Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 518:15 - 519:5; Fauci Exhibit 27 (5/9/2007 Judith Waterer 30(b)(6) Dep.), at 148:3 - 148:12; Fauci Exhibit 72 (7/24/2007 Judith Waterer Dep.), at 761:10 - 761:21) For example, the March 1998 price changes lowered the WACs for two of Roxane's diclofenac sodium products (NDCs 00054-4221-25 and 00054-4222-25) from $40.45 to $28.06 and from $45.53 to $31.23, respectively. (Fauci Exhibit 123, at Rox Tx 14601) Roxane did not reduce the AWPs for these products (which remained $86.13 and $104.31, respectively). (*Id.*)

128. On other occasions when Roxane *increased* WACs for products, personnel within Roxane's marketing department recommended corresponding AWP increases "in order to maintain the current spread." (Fauci Exhibit 125)

129. In accord with its decision to stop reporting WACs for multi-source products, Roxane did not report the new (reduced) WACs announced on March 16, 1998 to First Data Bank. (Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 518:3 -518:10; Fauci Exhibit 27 (5/9/2007 Roxane Dep.), at 153:20 - 154:23)

130. In addition, while Roxane did not lower any AWPs as part of its March 16, 1998 price change, Roxane *did* raise AWPs for certain (primarily branded or branded generic) products. (Fauci Exhibit 123, at Rox TX 14601 (e.g., the AWPs for Roxane's codeine phosphate solution and codeine sulfate tablets increased); *see also* Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 503:3 - 503:24) Although the March 1998 WAC changes were not reported to First Data Bank, Roxane did report the AWP increases. (Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 502:3 - 502:22, 518:3 - 518:14)

131. Mr. Tupa testified that not publishing the new WACs had the effect of preventing state Medicaid programs from learning of Roxane's most current WACs. (Fauci Exhibit 5 (1/31/2003 Edward Tupa Dep.), at 180:19 - 181:3)

2. Roxane Subsequently Took Steps to Remove Its WAC Pricing From First Data Bank

132. On or about October 14, 1999, James Rowenhorst (then "Reimbursement Manager") sent an email notifying Ms. Waterer and Ms. Paoletti (then an assistant to Ms. Waterer) that he had spoken with the Florida Medicaid Department regarding a "reimbursement issue" on one of Roxane's products. (Fauci Exhibit 126) Specifically, Mr. Rowenhorst noted that the Florida Medicaid program had changed its method of reimbursement and was "now reimbursing the pharmacist at the lowest price in the First Data Bank System, be it AWP, WAC (WHN) or Direct, plus 7%." (*Id.*) Mr. Rowenhorst asked Ms. Paoletti to validate that Roxane's most current prices were entered into First Data Bank and to verify that Roxane's old WAC and Direct Prices were "removed or updated." (*Id.*)

133. Ms. Paoletti subsequently attempted to have First Data Bank remove Roxane's WAC pricing from its database. (Fauci Exhibit 24 (11/9/2004 Leslie Paoletti Dep.), at 99:13 - 99:18) On or about October 20, 1999, Ms. Paoletti wrote a letter to First Data Bank, enclosing pricing corrections for Roxane's "Product Listing." (Fauci Exhibit 127) The cover letter to First Data Bank stated in relevant part:

> Thank you for the opportunity to provide First Data Bank with the most up to date product listing. Please note the corrections to pricing and discontinuations and remove inaccurate WAC pricing, where indicated. *Accurate WAC pricing will not be furnished,* as it is company policy not publish [sic] this information.

(*Id.*) (emphasis supplied) On the first page of Roxane's product listing (enclosed with the October 20, 1999 letter), Ms. Paoletti wrote "NP = Not Published." (*Id.*; *see also* Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 127:19 - 128:7) Ms. Paoletti crossed out the "WHLNET" (or WAC) price[3] for approximately 200 products on Roxane's product listing, and noted "NP" for each of these products instead. (Fauci Exhibit 127) Ms. Paoletti testified that where the WACs were not crossed out, it was likely because the product was either discontinued or part of Roxane's "branded" product line. (Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at 128:11 - 128:17)

134. On or about November 4, 1999, Mr. Rowenhorst sent an email to Ms. Waterer, stating that a pharmacist had complained because he was not receiving the "correct reimbursement" from Florida Medicaid. (Fauci Exhibit 126) Mr. Rowenhorst testified that First Data Bank's continuing publication of Roxane's WACs was an "obstacle to reimbursement" and that removing the WAC pricing was likely to result in higher reimbursement for at least some products. (Fauci Exhibit 128 (4/3/2003 James Rowenhorst Dep.), at 98:21 - 99:3 and 110:17 - 112:14)

135. On November 5, 1999, Ms. Paoletti notified Ms. Waterer that First Data Bank was now "willing to remove [Roxane's] WAC pricing from their database." (Fauci Exhibit 126) On or about December 7, 1999, Ms. Paoletti sent an email to Mr. Rowenhorst, stating that she had "received written confirmation from First Data Bank ***that all Multi-source product pricing except AWP has been updated to reflect a $0.00 price.***" (Fauci Exhibit 129) (emphasis supplied)

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[3]Ms. Paoletti agreed that the WHLNET prices were WAC prices. (Fauci Exhibit 19 (11/30/2005 Leslie Paoletti Dep.), at. 127:2-127:4)

136. Following Roxane's instruction to delete WACs, First Data Bank was left to publish only Roxane's AWPs for Roxane's multi-source products. (Fauci Exhibit 6 (4/1/2003 Judith Waterer Dep.), at 527:5 - 527:15) Roxane elected to remove WAC pricing for its multi-source products even though it was aware that several states used WACs. (Fauci Exhibit 48)

G. Roxane Knew or Should Have Known That Its Conduct Was Wrong

137. Roxane did not consider any laws or regulations relating in making decisions to set inflated AWPs. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 238:19 - 239:10, 283:4 - 283:19; Fauci Exhibit 130 (12/8/2008 Judith Waterer 30(b)(6) Dep.), at 140:15 - 142:7, 165:20 - 167:14, 142:20 - 144:3, 208:8 - 208:18) Nor did Roxane review or rely upon reports from the Office of Inspector General, Department of Health and Human Services, or other governmental agencies relating to allegations or findings that AWPs were inflated. (*Id.*)

138. By 1999, Roxane was aware that the government was investigating inflated AWPs in the pharmaceutical marketplace. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 54:19 - 54:22, 99:4 - 99:7, 172:13 - 172:16; Fauci Exhibit 2 (1/27/2005 Sheldon Berkle Dep.), at 229:16 - 229:13; Fauci Exhibit 131) Mr. Russillo, Roxane's director of multi-source marketing, testified that such investigations were a concern to him and to Boehringer Ingelheim in evaluating decisions regarding AWPs. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 166:7 - 166:9, 179:22 - 180:16)

139. In spite of such concerns, Roxane raised the AWPs on its furosemide products by as much as 300% in or around August 2000. (*See supra* Paragraph 84; *see also* Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 192:11 - 193:18) Roxane's new AWPs for its furosemide

products were as much as 10 times larger than its sales prices to customers. (Fauci Exhibit 3 (Platt Decl.), A5 Summary)

140. Mr. Russillo, who was involved in the decision to approve the increase in furosemide AWPs, testified that raising the AWP of a product to more than ten times its sales price did not concern him, so long as the AWP was increased to match a competitor's AWP. (Fauci Exhibit 13 (1/8/2009 Thomas Russillo Dep.), at 190:2 - 191:12 ("It doesn't matter what the number is. We were trying to be competitive."))

141. Likewise, in or around June 2000, Mr. Rowenhorst circulated an email including a Wall Street Journal Article entitled "Medicare Plans Major Overhaul, Targets Massive Overpayments." (Fauci Exhibit 132) The article specifically noted that "State and federal officials believe that some drug companies are reporting artificially inflated AWPs to industry guides that are used for government-reimbursement purposes." (*Id.*) Nevertheless, Mr. Rowenhorst recommended that Roxane continue to focus on higher AWPs as a way of staying competitive with Dey Laboratories in the home health care market:

> Depending on the results of HCFA's attempt to regulate prices for drugs in the Medicare program (see WSJ article below), the margins that the home health companies currently enjoy on the generic albuterol and ipratropium[] will be severely reduced. . .
>
> . . . In addition, generic ipratropium is not listed as a Federal Upper Limit Drug (otherwise known as Maximum Allowable Cost [MAC]) in the Medicaid system, however individual states have the authority to implement their own MACs.
>
> It is my recommendation, based on the reimbursement mechanisms in the retail, hospital and home health sectors, that we focus on a higher AWP and WAC and develop discount and rebate initiatives that will keep up compete [sic] with Dey in this market.

(*Id.*)

VI. ROXANE'S FALSE AWPS FOR ITS IPRATRIPIUM BROMIDE PRODUCTS CAUSED THE MEDICARE PROGRAM TO PAY MORE THAN IT WOULD HAVE PAID ABSENT THE FALSITY

142. The Court is respectfully referred to Paragraphs 1-16 of the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants (US-C-SF) for certain facts concerning Medicare Part B payment for DME drugs.

143. During the relevant time period, Medicare Part B paid claims for ipratropium bromide, when used in connection with durable medical equipment. (Henderson Common Exhibit 3 (Declaration of Carolyn Helton (hereinafter, "Helton Decl.")), ¶ 3) There were three different HCPCS codes used to process claims for ipratropium bromide. The HCPCS code J7645 was used from January 1, 1995 through March 31, 1997. The HCPCS code K0518 applied from April 1, 1997 through December 31, 1999. The HCPCS code J7644 applied from January 1, 2000, through the present. (*Id.*, ¶ 16)

144. The DMERC for Region D, CIGNA Government Services, Inc. ("CIGNA"), paid on behalf of Medicare many provider claims for reimbursement for ipratropium bromide. (Fauci Exhibit 134 (Declaration of Ian Dew (hereinafter, "Dew Decl.")), ¶¶ 9-13 and Exhibits C and D thereto)

145. CIGNA reimbursed for covered drugs at the lower of the allowable amount calculated by the carrier or the amount submitted by the provider in the claim. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 3)

146. CIGNA performed drug pricing calculations using AWPs data obtained from Red Book. (*Id.*, ¶ 9) In general, CIGNA performed drug pricing updates quarterly.

147. Generally, to determine the allowable fee for a particular DME drug, CIGNA used the Red Book to select the NDCs falling within the narrative description of the HCPCS code. CIGNA then created an array of prices that included the AWP for each selected NDC, using Red Book data. CIGNA converted each AWP to a unit price, so that there was a common measure of price. (*Id.*, ¶¶ 9-10)

148. Using the array, CIGNA then determined the median AWP for the NDCs in the array. If there was only one NDC with a published AWP in the array, CIGNA selected that price as the median. If there was an odd number of NDCs in the array, CIGNA selected the middle price. If there was an even number of NDCs in the array, CIGNA took the average of the middle two NDC prices to achieve a median. (*Id.*, ¶ 11)

149. The precise method followed by CIGNA for determining allowable reimbursement rates changed in the 1996-2003 period, in accordance with changing regulations or CMS instructions. (*Id.*, ¶ 12)

150. From 1994 through December 31, 1997, CIGNA calculated the allowable reimbursement rate as 100% of the median AWP of the generic forms of the drug (unless, as indicated above, only a brand drug was available). (*Id.*, ¶ 13)

151. Beginning January 1, 1998, as a result of the Balanced Budget Act of 1997, the DMERCs began paying providers at ninety-five percent of the median AWP. Accordingly, for quarters beginning January 1998, CIGNA calculated the allowable fee by multiplying the median AWP by 0.95. (*Id.*, ¶ 13)

152. Effective approximately January 1999, HCFA issued instructions to the DMERCs that the allowable fee was to be determined as the lower of the median of the generic sources of

the drug or the lowest priced brand name AWP. (*Id.*, ¶ 13, and at Helton Exhibit D) The transmittal further stated, "[a] brand name product is defined as a product that is marketed under a label name that is other than the generic chemical name for the drug or biological." (*Id.*)

153. The same instruction was repeated in Transmittal No. AB-99-63. (Fauci Exhibit 39)

154. Once CIGNA determined a new allowable fee for a HCPCS code, the new or updated price was entered into the electronic claims processing system used by the DMERCs for paying Part B claims, referred to as the ViPS Medicare System. Once a new or updated allowable fee was entered, the ViPS Medicare System used that price for determining the reimbursement of all applicable Medicare Part B claims that had not already been processed through the pricing part of the system. (Henderson Common Exhibit 3 (Helton Decl.), ¶ 14)

155. The arrays used by CIGNA to determine the allowable amount for ipratropium bromide from the third quarter of 1996 ("1996 Q3") through 2003 Q4 are at Exhibit A to the Declaration of Carolyn Helton, the CIGNA DMERC pricing analyst. (*Id.*, ¶ 16)

156. For quarters prior to 1997 Q2, the only product in the relevant array is Atrovent, the brand product marketed by Roxane's parent company, Boehringer Ingelheim Corp. Therefore Roxane's reported prices had no impact on the amounts paid by CIGNA for ipratropium bromide for claims processed before April 1, 1997.

157. For each the arrays for the quarters from 1997 Q2 through 2003 Q4, Roxane's products did appear in the arrays. (*Id.*, Exhibit A thereto) Dey's ipratropium bromide products also appeared in the arrays.

158. All of the arrays from 1997 Q2 through 2003 Q4 show the same median generic unit price, $3.52 per milligram, for K0518 and J7644. (*Id.*, Exhibit A thereto) During the period 1997 Q2 through December 31, 1997, the allowable amount determined by CIGNA for K0518 and J7644 was 100 percent of the median, or $3.52 per milligram. (*Id.*)

159. After January 1, 1998 (the effective date of the Balanced Budget Act of 1997), the allowable amount determined by CIGNA for K0518 and J7644 was 95 percent of $3.52, or $3.34. (*Id.*)

160. For the period 1997 Q2 through 2001 Q3, any reduction of one percent or more in the AWPs of the Roxane products (whether the AWP is expressed as a unit price or as the package price) would have lowered the median and therefore the Medicare allowed amount. (*Id.*, ¶ 24)

161. During the period April 1, 1997, through September 30, 2001, CIGNA processed for payment 1,076,790 claims for reimbursement for HCPCS codes K0518 or J7644. Of these,

910,835 claims were paid based on an allowed unit amount of either $3.52 or $3.34. (Fauci Exhibit 134 (Dew Decl.), ¶ 14)

DATED July 24, 2009

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s James J. Fauci
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Dated: July 24, 2009